RNK Products

K102893

510(k) SUMMARY
RNK Products
PCP/PC Stethoscope

JAN 2 0 2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:

Submitter Information

Submitter:	RNK Products 4195 US Hwy 1 Suite 101 Rockledge, FL 32955 Telephone: (321) 626-7717 Facsimile: (321) 305-5983
Contact Person:	Charles R. Abbruscato RNK Products Telephone: (321) 626-7717 Facsimile: (321) 305-5983
Date Prepared:	Sept. 3, 2010

Device Information

Name of Device	RNK PCP/PC Stethoscope
Common or Usual Name	Electronic Stethoscope
Classification Name	Electronic Stethoscope
Predicate Devices	RNK Products TR-1 Telephonic Stethoscope (034046) RNK Products Precordial Stethoscope (K072026)

Device Description

The PCP/PC Stethoscope is comprised of a PCP/PC Chest Piece that plugs into a generic PC on an IP network (e.g. the Internet) and the streaming Stethoscope Over IP (sSOIP) software application running on the PC. It provides remote auscultation between a patient at one location and a clinician at another location.

The PCP/PC Chest Piece derives operating voltage from the bias voltage on the Microphone port of the PC. PCP/PC Chest Piece contains an embedded amplifier which amplifies the auscultation signal from the piezo sensor and presents it as an analog signal to the Microphone input of the PC.

Under direction of the sSOIP program, the analog signal is digitized in the PC, formatted and converted to IP packets for transport. At the receive end PC, the sSOIP program directs the acceptance of the IP packets, conversion of the signal back to analog and presentation of the analog signal to the Headset port of the PC.

Intended Use

The RNK PCP/PC Stethoscope is intended for use as a remote monitoring device, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient at a different location on the IP network with the signal carried on an IP connection between the two locations.

Substantial Equivalence

The RNK PCP/PC Stethoscope uses a similar amplifier and chest piece sensor technology as the predicates. The RNK PCP/PC Stethoscope is substantially equivalent to the RNK Products, Inc. Telephonic Stethoscope Model TR-1 and Precordial Stethoscope. Bench testing and clinical testing was performed to verify specification and performance.

The RNK PCP/PC Stethoscope has the same intended use, principles of operation and technological characteristics as the predicate devices. There are no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 2 0 2011

RNK Products, Inc.
c/o Mr. Charles R. Abbruscato
CEO
12700 Diamond Drive
Burnsville, MN 55337

Re: K102893
Trade Name: RNK PCP/PC Telephonic Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD
Dated: January 12, 2011
Received: January 14, 2011

Dear Mr. Abbruscato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K102893

Device Name: PCP/PC Stethoscope

Indications for Use:

The RNK PCP/PC Stethoscope is intended to transmit auscultation sound data, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient at a different location on the IP network with the signal carried on an IP connection between the two locations.

Prescription Use: X OR Over-the-Counter Use _____
(Part 21 CRF 801 Subpart D) (Part 21 CRF 801 Subpart C)

(Please Do Not Write Below This Line – Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102893

(Optional Format 1-2-96)